Exhibit A

SUPERIOR COURT OF CALIFORNIA

COUNTY OF LOS ANGELES

AFL-CIO, et al., Plaintiffs, vs. ASTRAZENECA PHARMACEUTICALS LP, et al., Defendants	CASE NO. BC 323 107 RULING ON DEMURRER AND MOTION TO STRIKE

Hearing date: 8/11/05

Ruling date: 9/21/05

After considering the moving, opposing and reply papers the court now rules as follows:

The demurrers are OVERRULED as to the individual plaintiffs, SUSTAINED WITHOUT LEAVE TO AMEND as to the first and second causes of action (B&P §§ 17200 and 17500) brought by the associational plaintiffs, and OVERRULED as to the third and fourth causes of action brought by the associational plaintiffs.

The motions to strike are GRANTED as to Ledwick's prayer for treble damages and DENIED otherwise.

I. INTRODUCTION

From the complaints, the following facts appear. Defendants AstraZeneca Pharmaceuticals LP and Zeneca, Inc. marketed the drug Prilosec, a widely prescribed drug, used to treat acid reflux disease. The active molecule in Prilosec is omeprazole. Omeprazole exists in two mirror image forms (isomers), called the S-form and the R-form. Prilosec contains both forms, making what is called a "racemic" mixture. The patent for Prilosec was set to expire in 2001, at which time its value would decrease as generic drug manufacturers entered the market.

To preserve revenues, defendants developed Nexium, a drug that contains only the S-form of omeprazole, now called *es*omeprazole.

A Prilosec generic pill contains 20 mg of R- and S-omeprazole and costs $0.49. A Nexium pill contains 40 mg of esomeprazole and costs more than $4.00.

Plaintiffs allege defendants deceptively market Nexium.

The American Federation of Labor and Congress of Industrial Organizations (AFL-CIO), Congress of California Seniors (CCS), and California Alliance for Retired Americans (CARA) filed a lawsuit and later amended to add an additional plaintiff, James Weiss. The second amended complaint, hereafter the "Weiss complaint," is operative.

Kathleen Ledwick filed a separate lawsuit against the same defendants on the same causes of action. Her first amended complaint, hereafter the "Ledwick complaint," is operative. The two cases have been deemed related.

All plaintiffs allege violations of Business & Professions Code sections 17200 et seq. and 17500 et seq., violation of the Consumer Legal Remedies Act (CLRA), Civil Code § 1750 et seq., and unjust enrichment.

Defendants demur to both complaints and move to strike portions of both.

II. COMPLAINTS

Plaintiffs allege defendants falsely represented, in direct contact with physicians (Weiss, ¶ 64; Ledwick, ¶ 63) and advertising (Weiss, ¶ 62; Ledwick, ¶ 62) that Nexium is more effective than Prilosec when, in fact, it isn't. (Weiss, ¶ 65; Ledwick, ¶ 64.)

In its 2000 Annual Report, AstraZeneca claimed that "Nexium is the first [drug] to offer significant clinical improvements over *Losec* [Prilosec] in terms of acid control and clinical efficacy . . . . Nexium offers more effective acid inhibition than other [drugs] and in the treatment of reflux oesophagitis, provides healing and symptom relief in more patients and in a shorter period of time than *Losec*." (Weiss, ¶ 60; Ledwick, ¶ 60.)

Further examples of allegedly misleading promotion and advertising include advertisements found at ¶¶ 102, 104, 106, 108, 110, 112, 114, 16 and 118 of the Weiss complaint and corresponding paragraphs of the Ledwick complaint. Plaintiffs allege these advertisements are deceptive because they fail to disclose that Prilosec is as effective as Nexium. "The foregoing advertisements are just examples of the themes and messages conveyed in hundreds of advertisements distributed to doctors and/or consumers. The net effect of this misleading campaign was to establish Nexium as a superior drug for acid relief and as such to allow it to command a price substantially in excess of generic Prilosec." (Weiss, ¶ 120; Ledwick, ¶ 119.).)

Weiss alleges that he, "like all Class members, has purchased Nexium and has been harmed by defendants' misconduct because he would not have purchased Nexium had he known the truth." (Weiss, ¶ 123.) Ledwick alleges she, "like all Class members, has purchased Nexium and has been harmed by Defendants' misconduct. Had Astrazeneca not purposely and successfully created false beliefs among patients and doctors about Nexium's superiority, Plaintiffs would not have purchased Nexium at a premium over equally effective generic and OTC drugs . . . ." (Ledwick, ¶ 125.)

III. DEMURRERS

Defendants filed two demurrers, one to each complaint. Each demurrer incorporates the demurrers and arguments of the other. In the demurrer to the Weiss complaint, defendants object that plaintiffs lack standing under Business & Professions Code sections 17200 et seq. (UCL) and 17500 et seq., fail to allege causation sufficient to their CLRA claims, and fail adequately to allege unjust enrichment.

In the demurrer to the Ledwick complaint, defendants incorporate the above objections and additionally object that: 1) Federal law preempts plaintiffs' claims; 2) plaintiffs do not identify any factual statement in any advertisement that is false; 3) plaintiffs do not allege any advertisement conflicts with FDA-approved Nexium labeling; 4) plaintiffs' non-disclosure theory, that defendants should disclose that Prilosec is just as good as Nexium, conflicts with federal law because it is illegal to suggest to a consumer what drug he should take; 5) plaintiffs may not collaterally attack FDA approval of Nexium; and 6) no UCL, CLRA, or false advertising claim will lie where plaintiffs' only complaint is that a product was overpriced.

Because both demurrers and motions pertain to both complaints the court will combine them to examine all issues raised.

A. Proposition 64

Defendants first object that neither Weiss nor Ledwick has standing to allege violation of Business & Professions Code section 17200 et seq. or section 17500 et seq. because neither alleges he or she lost money due to defendant's unfair practices. (Undesignated statutory references are to the Business & Professions Code.) Defendants further objection that the associational plaintiffs lack standing because Proposition 64 did away with associational standing in the UCL and false advertising contexts.

Proposition 64, passed by voters in November, 2004, amended the standing requirements for actions under 17200 et seq. (UCL claim) and 17500 et seq. (false

advertising claim). To bring either a UCL or false advertising claim a plaintiff must now allege he or she personally lost money or property and that the loss was a result of defendant's misconduct. In effect, the Proposition 64 requires plaintiffs to allege and establish personal monetary injury and causation.

1. Damages

Both Weiss and Ledwick allege they purchased Nexium at a premium but would not have but for defendants' misconduct. (Weiss, ¶ 123; Ledwick, ¶ 125.) Defendants argue Weiss admits in his complaint that he used some free samples, made copayments, and received rebates (Weiss, ¶ 19) but does he not allege how long he received free samples, the amount of the copayment, how much "extra" he paid, or how much the rebates were. Therefore, defendants argue, Weiss does not allege he lost money or property, i.e., does not allege he was out of pocket. Perhaps, defendants argue, the copayment for Prilosec would have been the same or the rebates paid for the drug entirely.

This argument has some resonance in the complaint, wherein Weiss ambivalently alleges that he "paid extra but received rebates back from the manufacturer." (Weiss, ¶ 19.) However, a liberal reading of the complaint, which the court is required to give at this stage, recognizes that "paid extra" implies increased out-of-pocket expense and that manufacturer rebates rarely equal the purchase price of the product. Therefore, how much Weiss paid and was reimbursed are factual matters not to be resolved on demurrer.

Therefore, the demurrer on this ground is overruled.

2. Causation

Defendants next object that plaintiffs fail to allege they personally saw any of defendants' advertisements or representations, and that the advertising could not have caused plaintiffs' injury unless they themselves saw it.

Defendants offer no California authority supporting the argument and the court finds none. On the contrary, to establish causation it is "sufficient that defendant makes a misrepresentation to one group intending to influence the behavior of the ultimate purchaser, and that he succeeds in this plan." (*Committee on Children's Television, Inc. v. General Foods Corp.* (1983) 35 Cal.3d 197, 219; see also Rest.2d Torts, ¶ 533 ["The maker of a fraudulent misrepresentation is subject to liability for pecuniary loss to another who acts in justifiable reliance upon it if the misrepresentation, although not made directly to the other, is made to a third person and the maker intends or has reason to expect that its terms will be repeated or its substance communicated to the other, and that it will influence his conduct in the transaction or type of transaction involved."].)

Defendants attempt to get some mileage out of this court's recent statement in another case, *Fite v. Berkeley Premium Nutraceuticals, Inc.*, No. BC 313 557 (*Fite*), where it held that to establish causation a plaintiff must allege "plaintiffs' actual reliance on the representations and injury arising therefrom." (Slip op. at p. 6 (Cal. Super. Ct. May 10, 2005) (Chaney, J., presiding).) This statement will not take defendants far. In *Fite* defendant had argued that after passage of Proposition 64 a representative plaintiff alleging false advertising must allege and prove that *every class member* relied on the advertising. The court disagreed, reasoning that Proposition 64 pertained only to the representative's standing, not to the class's injury or causation thereof. Therefore, actual reliance was required merely to establish representative standing, after which the normal elements of the cause of action, e.g., representations that are reasonably likely to mislead, pertain. Accordingly the court held a plaintiff need not establish each class member's reliance, only his own. This holding did not abrogate well-settled third-party reliance law where, for example, injury to a patient may be caused by a pharmaceutical company's misrepresentations to a physician.

Even so, defendants argue, plaintiffs fail to allege their physicians saw AstraZeneca's advertising for Nexium, prescribed Nexium because of the advertising, or was swayed by the advertising from his or her independent medical judgment.

This argument, too, is without merit. Upon demurrer the court must construe the complaint liberally, taking as true all material facts alleged and all reasonable inferences that may be drawn from those facts. Plaintiffs allege at length that defendants directed their advertising at physicians and that plaintiffs would not have purchased Nexium, a prescription drug, but for defendants' advertising. It is reasonable to infer from this that plaintiffs' physicians became aware of the advertising and were influenced by it. Whether they were influenced in fact may not be resolved by demurrer.

Therefore, the demurrer on this ground is overruled.

3. Associational Standing

The AFL-CIO, CCS and CARA were not personally injured by defendants' alleged misrepresentations—they assert only "associational standing." To establish such standing an association "must demonstrate that its members would otherwise have standing to sue in their own right." (*Associated Builders & Contractors, Inc. v. San Francisco Airports Comm'n* (1999) 21 Cal.4th 352, 361.) Defendants argue Proposition 64 eliminated common law associational standing.

The court agrees. Before Proposition 64, sections 17204 and 17535 provided that a UCL or false advertising claim could be brought by "any person acting for the interests of itself, *its members* or the general public." (*Ibid.*, emphasis added.) Now, sections 17204 and 17535 provides that such claims may be brought only by "any person who has suffered injury in fact and has lost money or property . . . ." (*Ibid.*) By removing the reference to an association's "members," and by requiring injury to plaintiffs' own finances, the voters indicated their intent to eliminate associational standing in the UCL and false advertising contexts.

Therefore, the demurrer to the first and second causes of action, for violation of Business & Professions Code sections 17200 et seq. and 17500 et seq., respectively, is sustained without leave to amend as to the AFL-CIO, CCS and CARA.

B. Federal Issues

Defendants' next round of objections, presented in the demurrer to the Ledwick complaint and incorporated by reference into the demurrer to the Weiss complaint, follow a theme fueled by several defects in both complaints. Defendants argue that because Prilosec advertising comports with federal law and the allegedly non-deceptive alternatives proposed by plaintiffs don't, plaintiffs' decrial of the advertising is preempted or barred by federal law. Defendants offer a number of avenues to reach this conclusion--federal preemption, FDA regulation, the First Amendment--all following the theme: Plaintiffs allege that activity permitted by federal law is wrongful and that activity prohibited by federal law is proper; federal law controls; therefore plaintiffs' claims are barred or preempted.

The argument finds its ground in the complaints themselves. Overarchingly, the complaints allege defendants purposed to preserve market share by misrepresenting that Nexium is better than Prilosec. Defendants effected their purpose through direct communication with physicians, direct advertising to physicians, targeted advertising, and general advertising. As a legal conclusion it cannot reasonably be denied that misrepresenting one product as better than another constitutes false advertising unprotected by federal law. That defendants directly communicated this misrepresentation to physicians suffices to state plaintiffs' claim and preserve the complaints against demurrer.

But plaintiffs go further. First, in a section entitled "Further examples of Misleading Promotion and Advertising," they attach Nexium advertising to the complaints. (Weiss, ¶¶ 102-120; Ledwick, ¶¶ 101-119.) Plaintiffs allege the "advertisements are just examples of the themes and messages conveyed." (Weiss, ¶ 120; Ledwick, ¶ 119.) The advertising, however, does not appear to support plaintiffs' claims. Most of it does not mention Prilosec and that which does, does so neutrally.

Next, plaintiffs make much of an AstraZeneca annual report touting the virtues of

Nexium over Prilosec. (Weiss, ¶ 7; Ledwick, ¶ 7.) However, it is not clear how widely this report was disseminated or whether defendants intended it to constitute advertising.

Perhaps to supplement the facial neutrality of "exemplar" advertising, plaintiffs suggest defendants' implied misrepresentations and concealment of material facts create an aura of deception: Defendants failed to disclose that test results on the relative efficacy of Nexium and Prilosec are ambiguous or that dosage manipulation would equalize the efficacy of Nexium and Prilosec.

1. Preemption

In their demurrer to the Ledwick complaint defendants first object that plaintiffs' claims are preempted by federal law. Defendants preface the argument by contending plaintiffs "fail[] to point to any statement in any advertising of Nexium that [they] assert[] is false." (Ledwick Dem., Pts. & Auth., p. 8.) "Rather," defendants argue, plaintiffs "attack[] a claim of superiority that [they] contend[] is implicit in AstraZeneca's advertising and that should have been cured by a disclosure that Prilosec in a double dose is equally effective." (*Ibid.*) This claim fails, defendants argue, because the implied message of superiority is not inconsistent with federally approved labeling and advertising that complies with FDA requirements is immune from attack under California law.

The court will attempt to unwind the numerous issues the argument presents.

At the outset, even if defendants' preemption argument were meritorious it would not be ground for sustaining the demurrer because plaintiffs do not allege only an implied message of superiority (and improper cure therefor), they also allege defendants explicitly represented to physicians and consumers that Nexium is superior to Prilosec. (Weiss, ¶¶ 59, 61, 62, 64 ; Ledwick, ¶¶ 59, 61, 62, 63 ["AstraZeneca spent $98 million on direct-to-consumer promotions, again claiming Nexium was superior to Prilosec."].) It may be this allegation of explicit representation of superiority is groundless—plaintiffs

give no citation of text, either in paragraph 62 ("'we've captured the essence of Prilosec and created a new PPI . . . introducing Nexium the powerful new PPI from the makers of Prilosec'") or the exemplar advertising to support it. But the allegation states a fact that upon demurrer must be accepted as true: Defendants explicitly represented to consumers that Nexium is better than Prilosec.

Defendants first argue plaintiffs fail to identify any factual statement in any ad that is false. This is a correct statement, but failure to identify false factual statements in advertising is not ground for demurrer where plaintiffs also allege misleading factual statements made directly to consumers, not through advertising.

Defendants next argue plaintiffs' allegation of a misleading message is preempted by federal law because an attack on advertising that does not conflict with Nexium's FDA-approved labeling would infringe on the FDA's exclusive authority to approve drugs and contradict the FDA's implicit finding that the labeling is not misleading.

A civil lawsuit under state law is preempted where the state law establishing liability conflicts with federal law that permits the challenged conduct. (*Geier v. American Honda Motor Co.* (2000) 529 U.S. 861, 899.) Assuming drug labeling or the FDA's authority to prescribe it qualify as federal law for purposes of a preemption analysis, defendants do not explain, and the court cannot fathom, how Nexium's labeling affirmatively supports defendants' claim that Nexium is superior to Prilosec. The court is unaware of any allegation that Nexium's labeling even mentions Prilosec, much less demonstrates Nexium's superiority to it. Additionally, the court is unaware of any allegation that the promotional statements at issue were derived by defendants from Nexium labeling. Rather, it appears the challenged statements arose after Nexium was approved and do little, if anything, to reference the labeling. Even if the advertising were somehow derived from the labeling it would be nonsensical to hold all advertising valid or immunized simply because it does not "conflict" with the labeling. If all advertising were permissible simply because it does not conflict with the label a manufacturer could say virtually anything, so long as he avoids the label's limited purlieu. (A claim that

snake oil cures dandruff does not conflict with the label identifying the oil as coming from a snake.)

Defendants next argue that, "unable to point to any actionable misstatement," plaintiffs allege defendants' advertising is misleading because it fails to disclose that "double the standard dose of Prilosec would be "equally as effective" as a 40 mg does of Nexium. "E.g, [Weiss compl.] ¶¶ 6, 41, 102, 104, 106, 108, 110, 112, 114, 116, 118." (Ledwick dem., pts. & auth., p. 13.) Such a disclaimer, defendants argue, would be conflict with federal law.

This argument comprises a faulty premise followed by a strawman. As discussed above, plaintiffs' *have* pointed to an actionable misstatement. And nowhere do plaintiffs allege defendants' advertising is misleading because it fails to disclose that a double dose of Prilosec is as effective as a single dose of Nexium. The court need not determine whether a disclaimer nobody espouses would conflict with federal law.

Defendants argue plaintiffs cannot challenge the FDA's approval of a 40 mg dose of Nexium.

Plaintiffs bring no such challenged.

Defendants argue plaintiffs cannot collaterally attack the FDA's approval of Nexium.

Plaintiffs mount no such attack.

Finally, defendants argue plaintiffs cannot state a claim based on defendants charging too much for Nexium.

Predatory pricing does not form the basis of any of plaintiffs' claims.

Defendants' demurrer on the ground of preemption is overruled.

2. First Amendment

Defendants argue plaintiffs' claims are barred by the First Amendment because states may not burden commercial speech either by imposing restrictions on speech that

is not false or misleading or by requiring the further disclosures plaintiffs espouse (regarding the quality of Nexium in relation to Prilosec or its pricing or dosage).

This argument fails for the same reason defendants' preemption argument fails: It is based on a faulty premise, that its speech is not alleged to be false or misleading, and on mischaracterization of the complaints. Therefore, the demurrer on this ground is overruled.

3. Abstention Doctrine

In a similar vein, defendants argue the court should decline to exercise its equitable jurisdiction in what is essentially a regulatory matter because the FDA, which has issued a complex web of regulations, holds extensive investigatory and enforcement authority, and subjected Nexium to rigorous testing is better able to cure any deceptive advertising.

Defendants admit no California appellate court has addressed abstention in the context of a false advertising claim. This court is not satisfied the FDA, which evaluates the safety and efficacy of drugs, wishes to concern itself overmuch with the UCL and false advertising claims plaintiffs assert here. Plaintiffs do not challenge the safety or efficacy of Nexium. Nor do plaintiffs allege defendants' advertising leads to some risk of physical harm. Rather, plaintiffs allege defendants' practices impact consumer pocketbooks. The court is unaware of any FDA interest in such matters. Therefore, the demurrer on this ground is overruled.

4. Safe Harbor

Repeating its preemption argument in part, defendants argue its advertising is not actionable under the UCL because it is not inconsistent with the FDA-approved labeling. (*Cel-Tech Communications, Inc. v. Los Angeles Cellular Tel. Co.* (1999) 20 Cal.4th 163,

182.) The argument fails as discussed above. Therefore, the demurrer on this ground is overruled.

C. Conclusion

Defendants' demurrer to the first and second causes of action, for violation of Business & Professions Code sections 17200 et seq. and 17500 et seq., respectively, is sustained without leave to amend as to the AFL-CIO, CCS and CARA and overruled as to the individual plaintiffs. Defendants' demurrer to the third and fourth causes of action is overruled.

IV. MOTIONS TO STRIKE

A. Privilege

Defendants move to strike a number of allegations relating to their actions in obtaining FDA approval for Nexium and patents for Prilosec and in bringing actions against generic competitors. Defendants object to these allegations n the ground this activity is privileged under Civil Code section 47 (the litigation or petition privilege) and therefore allegations pertaining to them are irrelevant.

The court does not understand plaintiffs to predicate their claims on this activity but rather on how defendants communicated with physicians and consumers. Plaintiffs describe the (arguably) privileged activity not to establish liability but to evidence defendants' plan to maintain its market share (which plan drove defendants' advertising campaign) and their knowledge of the relative benefits of Nexium. The allegations constitute neither improper nor irrelevant matter. Therefore, the motion to have them stricken is denied.

B. CLRA Damages

Defendants move to strike plaintiffs' claims for CLRA damages on the ground plaintiffs' CLRA notice-and-demand letter was deficient.

Subdivision (a) of Civil Code section 1782 provides that:

> Thirty days or more prior to the commencement of an action for damages pursuant to this title, the consumer shall do the following: . . . (1) Notify the person alleged to have employed or committed methods, acts, or practices declared unlawful by Section 1770 of the particular alleged violations of section 1770.

This notification procedure cannot be liberally construed. (*Outboard Marine Corp. v. Superior Court* (1975) 52 Cal.App.3d 30, 40.) "[A] class demand letter under the [CLRA] should set forth, as explicitly as possible, the objected-to practices, the relief requested, and the intent to file a class action should the letter's demands not be met." (*Kagan v. Gibraltar Sav. & Loan Assn.* (1984) 35 Cal.3d 582, 594.) "The purpose of the notice requirement of section 1782 is to give the manufacturer or vendor sufficient notice of alleged defects to permit appropriate corrections . . . ." (*Outboard Marine, supra*, at p. 40.)

Plaintiffs' notice-and-demand letters stated that "AstraZeneca has engaged in consumer fraud, false and misleading advertising and deceptive practices in connection with the sale of the Nexium product" and "[i]n particular, . . . has violated §§ 1770(a)(5), (7), (8), and (9)." (CLRA Amendments to Complaints, Exh. A.) The letters were sent after the complaints were filed and reference them. (*Ibid.*)

Defendants argue this notice is inadequate because it does not describe the allegedly deceptive practices and does not indicate what advertising or other activity is misleading.

The argument is without merit. Plaintiffs' letters identify the particular subsections of Civil Codes section 1770 that have been violated and reference complaints in which the violations are described in detail. This notice suffices. Therefore, defendants' motion to strike the prayer for CLRA damages is denied.

C. Treble Damages

Defendants move to strike Ledwick's prayer for treble damages on the ground that no applicable statute permits treble damages.

Ledwick seeks "Treble damages and all other penalties as allowed by law." (Ledwick compl., prayer, ¶ C.)

Ledwick responds that she does not seek "treble" damages, but instead seeks the triumvirate of damages permitted by the CLRA: actual, punitive and additional damages for senior citizens and disabled persons.

The complaint seeks "treble damages," not a triumvirate of damages. Plaintiff identifies no statute entitling her to treble damages. Therefore, the motion to strike the prayer for them is granted.

In Sum:

The demurrers are OVERRULED as to the individual plaintiffs, SUSTAINED WITHOUT LEAVE TO AMEND as to the first and second causes of action (B&P §§ 17200 and 17500) brought by the associational plaintiffs, and OVERRULED as to the third and fourth causes of action brought by the associational plaintiffs.

The motions to strike are GRANTED as to Ledwick's prayer for treble damages and DENIED otherwise.

IT IS SO ORDERED.

Dated: 9/21/05

Victoria Gerrard Chaney

Judge